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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,641	07/16/2003	Wayne V. Vedeckis	Vedeckis 97M20-D	1702

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,641

Applicant(s)

VEDECKIS ET AL.

Examiner

Nirmal S. Basi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to a hGR 1 Ap/e gene comprising SEQ ID NO:1 or fragments thereof, mRNA transcript produced by said gene and hGR 1 Ap/e promoter-heterologous gene product, classified in class 536, subclass 23.1, for example .
 - II. Claims 8 -10, drawn to a method to detect the presence of cancerous lymphocytes in a human comprising assaying for the expression of the mRNA transcript of claim 7 using primers chosen from the sequence from +308 to +981 of SEQ ID NO:1, classified in class 435, subclass 6, for example.
 - III. Claims 11-12, drawn to a method to increase the expression of the mRNA of claim 7 by adding an exogenous substance that causes an increased concentration of interferon regulatory factor, wherein the interferon regulatory factor binds the DNA of SEQ ID NO:1 between nucleotides +102 and +125, classified in class 435, subclass 91.1.
 - IV. Claim 13, drawn to a method to increase the expression of the mRNA of claim 7 to treat a patient with T-cell acute lymphoblastic leukemia cells, comprising administering to the patient an enhancing amount of exogenous interferon and exogenous glucocorticoid, classified in class 514, subclass 2.

- V. Claim 14 and 15, drawn to a method to increase the expression of the mRNA of claim 7 to treat a patient with T-cell acute lymphoblastic leukemia cells, comprising administering to the patient an enhancing amount of an exogenous demethylating agent to reactivate the human glucocorticoid promoter and exon 1A activity, classified in class 514, subclass 241.
- VI. Claims 16 and 17, drawn to a hGR 1 Ap/e promotor-heterologous gene construct comprising all or portion of SEQ ID NO:1 and a heterologous gene, classified in class 536, subclass 23.4, for example .
- VII. Claim 18, drawn to method to kill targeted cells by administering an exogenous dose of glucocorticoid comprising transforming targeted cells by introducing into said cells the gene construct of claim 17, classified in class 435, subclass 375.
- VIII. Claim 19, drawn to a method to convert glucocorticoid-resistant lymphoblasts to glucocorticoid-sensitive lymphoblasts comprising introducing all or functional portion of SEQ ID NO:1 into hormone resistant lymphoblasts, classified in class 514, subclass 44.
- IX. Claim 20, drawn to an antisense transgene comprising all or a functional portion of the promoter region of SEQ ID NO:1 linked to a fragment of the exon region of SEQ ID NO:1 in the antisense orientation, classified in class 536, subclass 24.5.

- X. Claim 21, drawn to a method to inhibit hGR 1 mRNA from being up-regulated in cells comprising introducing into said cells the antisense trans gene of claim 20, classified in class 435, subclass 91.1.
- XI. Claim 22, drawn to a method to prevent neuronal apoptosis caused by excessive glucocorticoid secretion comprising introducing into said neuronal cells the antisense trans gene of claim 20, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

The compounds of Inventions I and the methods of Inventions II-IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used to produce the encoded protein, which in turn can be used for the production of antibodies.

The compounds of Invention I are distinct from the methods of Invention VII and X-XI wherein the compounds of Invention I can neither be used in nor made by the methods of Invention VII and X-XI.

The compounds of Inventions VI and the methods of Invention VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

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used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the fusion gene construct of invention VI can be used to produce the encoded protein, which in turn can be used for the production of antibodies.

The compounds of Invention VI are distinct from the methods of Invention II-V, VIII and X-IX wherein the compounds of Invention II can neither be used in nor made by the methods of Invention II-V, VIII and X-XI.

The compounds of Inventions IX and the methods of Invention X-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid construct of invention IX can be used in hybridization assays.

The compounds of Invention IX are distinct from the methods of Invention II-VII, wherein the compounds of Invention IX can neither be used in nor made by the methods of Invention II-VII.

The compounds of Inventions I, VI and IX are distinct from each other because they have distinct functional, chemical and physical properties and the compounds are capable of separate use and manufacture.

The methods of Invention II-V, VII-VIII and X-XI are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-XII would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

An election to prosecute one of the groups listed I-XI must be made. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
Nirmal S. Basi
Art Unit 1646
6/23/06


ROBERT S. LANDMAN, PH.D.
PATENT EXAMINER